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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Refer to: CFN 1125229

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M3408m

Food and Drug Administration
Baltimore District Office
Central Region
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396
FAX: (410) 962-2307

March 10, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Valerio Calcagno, President
Vace, Inc.
3315 Connecticut Avenue, N.W.
Washington, DC 20008-1302

Dear Mr. Calcagno:

A Food and Drug Administration (FDA) inspection of your food manufacturing operation, located at 7601 A Airpark Road, Gaithersburg, Maryland, was conducted on February 8 and 23, 2000. During the inspection, labeling for your Cheese Ravioli, Cheese Capeletti, Spinach & Cheese Lasagna, and Spinach & Cheese Canneloni with Sauce products was collected. Review of the labels revealed violations of the Nutrition Labeling and Education Act (NLEA) and Title 21, Code of Federal Regulations (CFR), Part 101. More specifically, we have determined that your products are misbranded, in that they fail to bear nutrition labeling as required under Section 403(q)(1) of the Federal Food, Drug and Cosmetic Act (the Act) and Title 21, CFR, Part 101.9. The labels are not exempt per Section 403(q)(5) of the Act from the requirements of the NLEA, since your foods are shipped in packaged form from your manufacturing site in Gaithersburg, Maryland to your retail establishment located at 3315 Connecticut Avenue, N.W., Washington, DC.

Please be advised that the label review revealed the following additional deviations for the products listed:

Cheese Capeletti:

Our investigator determined that your firm utilizes two different means of packaging and two different labels for this product, as follows:

- (1) Use of a plain plastic bag with the stick-on label, labeled in part: “ ** CHEESE ** CAPELETTI ** INGREDIENTS: FLOUR, EGG, WATER, SALT ** VACE ** (202) 363-1999 ** (301) 654-6367 ** ”
- (2) A pre-printed plastic bag labeled in part: “ ** VACE ** CHEESE ** CAPELETTI ** DOUGH INGREDIENTS: FLOUR, EGG, WATER, SALT ** MANUFACTURED BY VACE, INC. ** GAITHERSBURG, MD. 20879 ** NET WT. (16 OZ.) 1 LB. (454g) ** KEEP FROZEN ** ”

Mr. Valerio Calacagno

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The plain plastic bag with stick-on label is misbranded within the meaning of Section 403(e)(1) of the Act, in that it does not contain the place of business of the manufacturer, packer, or distributor as set forth in 21 CFR 101.5(d). In addition, the label is misbranded within the meaning of Section 403(e)(2) of the Act, in that it does not contain the declaration of net quantity of contents as set forth in 21 CFR 101.105.

Spinach & Cheese Lasagna and Spinach & Cheese Canneloni with Sauce:

The stick-on labels for both products are misbranded within the meaning of Section 403(e)(1) of the Act, in that they do not contain the place of business of the manufacturer, packer, or distributor as set forth in 21 CFR 101.5(d).

The above violations concern certain new and current labeling requirements and are not meant to be an all-inclusive list of deficiencies. Labeling violations such as these may cause the product to be adulterated or misbranded within the meaning of the Act and, as such, subject to legal action without further notice, such as seizure and/or injunction. It is your responsibility to assure that all of your products are labeled in compliance with all applicable regulations enforced by the FDA. Information regarding the food labeling regulations may be obtained through the Internet at <http://www.fda.gov>.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, along with copies of the revised labels. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Northern Virginia Resident Post, at 101 W. Broad Street, Suite 400, Falls Church, Virginia 22046, to the attention of Gerald W. Miller, Compliance Officer. Mr. Miller may be reached at 703-235-8440, extension 504.

Sincerely,



Lee Bowers
Director, Baltimore District

cc: Juan A. Chavarria
Supervisor/Sanitation Manager
Vace, Inc.
7601 A Airpark Road
Gaithersburg, MD 20879